WILMERHALE

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John J. Regan

+1 617 526 6120 (t)
+1 617 526 5000 (f)
john.regan@wilmerhale.com

Honorable Alison J. Nathan
United States District Judge
Thurgood Marshall United States Courthouse
40 Foley Square, Room 906
New York, New York 10007

Re: *Braintree Laboratories, Inc. v. Breckenridge Pharmaceutical, Inc.*, Civil Action No. 12-cv-6851-AJN [rel. 14-cv-8147-AJN]

Dear Judge Nathan:

This firm represents Plaintiff Braintree Laboratories, Inc. ("Braintree") in the above-referenced matter. Pursuant to the Court's March 2, 2015 Order (Dkt. No. 74), Braintree respectfully submits this letter to notify the Court of the further action that has occurred in *Braintree Laboratories, Inc. v. Novel Laboratories, Inc.*, Civil Action No. 3:11-cv-01341 ("the Novel case"), and to set out, for the Court's consideration, Braintree's recommendations on next steps in this litigation. The parties could not reach agreement on a joint proposal to the Court, so they agreed to submit separate letters which they have exchanged and reviewed in advance of filing.

Current Status of the Novel Case

On June 2, 2015, District Judge Peter G. Sheridan of the District of New Jersey issued his findings of fact and conclusions of law, following a remand trial, solely on infringement, that took place from February 9 through 11, 2015. Judge Sheridan's opinion and final judgment are attached to this letter as Exhibits A and B. Judge Sheridan found that Novel Laboratories, Inc.'s ("Novel") proposed generic copy of Braintree's colonoscopy preparation SUPREP would, if marketed and sold, infringe claims 15 and 18, and induce infringement of claims 19, 20, and 23 of U.S. Patent Number 6,946,149 (the "'149 Patent"). Novel filed a notice of appeal with the U.S. Court of Appeals for the Federal Circuit on June 2.

Judge Sheridan's final order of judgment omitted reference to the injunction that he had ordered after the original trial. On June 4, Braintree moved under Federal Rule 59(e) for an amended judgment reinstating the original injunction—enjoining the FDA's final approval of Novel's ANDA and enjoining Novel from, *inter alia*, making, using, or selling its proposed product. That motion remains pending. The Federal Circuit docketed Novel's appeal on June 4, 2015.

The Administrative Stay

On January 17, 2014, this Court ordered, on consent of the parties, this matter administratively stayed "in the interests of efficiency," until resolution of the first appeal in the Novel case. Dkt. No. 65. The parties submitted a joint letter on April 29, 2014 requesting that the stay continue pending resolution of the Novel remand. Dkt. No. 68. On April 30, 2014, the Court granted that request. Dkt. No. 69. On August 13, 2014, the parties submitted a joint letter requesting that the administrative stay remain in place pending resolution of the remand in the Novel case. Dkt. No. 70. The Court ordered the case so stayed. Dkt. No. 71. On March 2, 2015, the Court again ordered that the stay continue pending completion of the Novel remand. Dkt. No. 74.

In the interests of conserving judicial resources and the parties' resources, and for the same reasons that the Court first ordered the stay, the administrative stay should continue until the

Federal Circuit resolves Novel's appeal. First, the Novel case's outcome may be relevant to this matter, determining infringement of the same patent claims and accused product as are at issue here. As the parties jointly stated in their April 29, 2014 letter, staying this case pending the Novel case "favors judicial economy and is in the best interests of the parties." *See* Dkt. No. 68.

Second, as the Court stated in its March 2, 2015 Order, Breckenridge, pursuant to the procedural stipulation entered between the parties, "will be permitted to rely upon any final judgment of non-infringement obtained in the Novel Case, whether at the Federal Circuit or upon remand to the District Court." Dkt. Nos. 74, 41. Because Breckenridge may rely upon any noninfringement holding by the Federal Circuit in the Novel case, the more reasonable course is to allow the Novel case to proceed to avoid spending resources unnecessarily. The reasoning set forth in the Court's March 2, 2015 Order remains fully applicable. If Judge Sheridan's infringement order is affirmed, the parties can recommend at that time the next steps in this case.

Third, although Breckenridge argues that purported regulatory developments make resolution of this matter "more urgent," it was Breckenridge, not Braintree, that urged that its early motion for summary judgment should supplant discovery, claim construction, and the ordinary course of events in this litigation. To obtain permission to file a pre-discovery summary judgment motion, Breckenridge stipulated, *inter alia*, that its only defense to infringement is the volume argument in its motion, and that Breckenridge could rely upon any final judgment of non-infringement in the Novel case. As the Court stated in its March 2, 2015 Order, this stipulation was a "primary basis for the Court's prior decision to grant the parties' jointly requested stay of this action." *See* Dkt. No. 74. Now that Braintree has proven infringement twice in the Novel case, and the Federal Circuit has upheld the validity of Braintree's patent, Breckenridge seeks to maneuver outside its stipulation. But none of the purported regulatory developments changes the impact of Breckenridge's stipulation, which supports a continued stay in this case now, as before.

The purported regulatory developments that Breckenridge cites to show urgency are speculative. Novel might have forfeited its 180-day exclusivity. The FDA will likely make that determination when, and if, Novel, or some other entity, receives final regulatory approval. The FDA's significant delays in approving ANDAs are well-known and have been the subject of Congressional legislation. *See, e.g.*, FDA Safety and Innovation ACT § 1133. The apparent delay in the FDA's approval of Novel's ANDA may or may not be cause for Novel eventually to forfeit its 180-day exclusivity—but that is all speculation. *See* 35 U.S.C. § 355(j)(5)(D)(i)(IV).

Breckenridge never addresses the statutory exception to forfeiture in § 355(j)(5)(D)(i)(IV). That exception provides that failure to obtain tentative approval is grounds for forfeiture "unless the failure is caused by a change in or a review of the requirements for approval of the application imposed after the date on which the application is filed." *Id.* Breckenridge has made no assertion that this statutory exception is not relevant to Novel's ANDA. The absence of any facts regarding this exception is further evidence of Breckenridge's speculation.

Breckenridge also speculates, without any supporting documentation from the FDA, that it may "in the near term" or in "a few months" receive final FDA approval for its proposed generic copy of SUPREP. There is no basis for this assertion. Novel only recently received tentative FDA approval, some ***four and a half years*** after filing its ANDA. Breckenridge filed its ANDA nearly two years after Novel's, and Breckenridge still awaits FDA approval. Breckenridge is also assuming that its ANDA is next in line to Novel's in order of filing. That is not correct. Braintree is not aware of any reason to expect that Breckenridge will receive tentative—let alone final—approval imminently just because Novel recently received tentative approval. Nor has Breckenridge told Braintree that an at-risk launch of its generic copy of SUPREP is imminent.

There is no basis to conclude that continuation of the stay would deprive the public of lower cost generics—especially when regulatory approval for Breckenridge's proposed generic copy of SUPREP has not occurred, and no date for approval has been suggested by FDA. Consequently, there is no reason to expect a preliminary injunction motion in this case in the near future.[1]

For all these reasons, Braintree respectfully proposes that this Court continue the administrative stay and order the parties to submit a joint status letter to this Court within six months.

The Breckenridge Motion

In the event that the Court denies Braintree's request to continue the administrative stay, and the Court decides to consider Breckenridge's Motion for Summary Judgment, Braintree requests permission for further briefing on the impact of the Federal Circuit's decision in the Novel case, and any relevant authority that has issued since the parties briefed the Motion in 2013. Braintree further requests that the Court allow a reasonable period of time for such briefing, beyond the June 23 date proposed by Breckenridge.

Further briefing is warranted because the Federal Circuit's opinion foreclosed Breckenridge's proposed "volume" argument. Judge Dyk raised Breckenridge's volume argument during both Novel's and Braintree's oral arguments. Novel responded by arguing that the volume limitation provided an independent basis to find noninfringement. *See* Oral Argument at 1:00, 15:20, *Braintree Labs., Inc. v. Novel Labs., Inc.*, No. 2013-1438 (Fed. Cir.) ("*Novel CAFC*"), *available at* http://oralarguments.cafc.uscourts.gov/Audiomp3/2013-1438.mp3. Judge Dyk agreed with Novel's volume oral argument, and on that basis dissented-in-part.[2] *Novel CAFC*, Dkt. No. 56.

The opinion's structure demonstrates that the panel majority did not adopt Judge Dyk's view and Breckenridge's "volume" argument. *See Matter of Mem'l Estates, Inc.*, 950 F.2d 1364, 1367 (7th Cir. 1991); *Jones v. Lewis*, 957 F.2d 260, 262 (6th Cir. 1992) ("In determining the scope of an appellate mandate, the majority, concurring, and dissenting opinions may be consulted."). The other two judges necessarily considered the argument when they heard it and read Judge Dyk's dissent. Neither adopted the argument. The Federal Circuit's mandate and opinion defining the scope of the remand did not direct Judge Sheridan to address the volume issue.

The Federal Circuit rejected Novel's petition for rehearing *en banc* on this precise issue, when Novel briefed it to press the points in Judge Dyk's dissent. *Novel CAFC*, Dkt. Nos. 61, 85.

In addition, Judge Sheridan previously ruled against Breckenridge's volume argument, after Novel made it at length in its motion for summary judgment. *See* Novel case, Dkt. No. 161, at 34-50 (Novel Summary Judgment brief). Novel argued, like Breckenridge, that administration of one diluted bottle of SUPREP to cause purgation is an "off-label use" under Federal Circuit precedent. Judge Sheridan ruled that this argument was "without merit." *See* Dkt. 46-15, at 16.

Given the rejection of Breckenridge's argument by the Federal Circuit, all that remains in this case is Breckenridge's potential ability to rely upon any final judgment of noninfringement in the Novel case. That is further reason for the existing administrative stay to be continued.

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[1] Breckenridge singles out one purpose of the Hatch-Waxman Act—bringing "cheaper, generic drugs to market" quickly. But Congress also recognized the importance of allowing pioneer drug makers to bring infringement suits before a generic copy is approved and marketed. This protects the NDA holder's substantial investment in innovation and clinical trials in exchange for the savings that ANDA applicants achieve from using the NDA holder's clinical study data.[1] *See, e.g., Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 676-77 (1990) (describing the ANDA approval process and the "important new mechanism" of §271(e)(2) infringement "designed to guard against infringement of patents relating to pioneer drugs").

[2] The Federal Circuit has discretion to consider an argument not raised in the parties' briefs. *See, e.g., Litecubes, LLC v. N. Light Products, Inc.*, 523 F.3d 1353, 1369 (Fed. Cir. 2008).

Respectfully submitted,

/s/John J. Regan

John J. Regan

Cc: All counsel of record (via email)